

Appl. No. 10/027,343
Amendment dated September 9, 2003
Reply to Office Action of August 4, 2003

REMARKS**A. Claim rejection under 35 U.S.C. §102**

1. The instant invention is patentable over Freitas et al; U.S. Pat. No. 5,486,185 ('185); as it embodies a moving shaft (prime mover 130) received within a fixed hollow manipulation shaft (120), thereby imparting a physical difference over the prior art that results in considerably improved functionality.

The Examiner has rejected claims 1, 4, 10, 11, 15, 16, 19 – 21, 24, 25, 29, 32, 36 and 37 under 35 U.S.C. §102(b) as being anticipated Freitas et al. (U. S. Patent No. 5,486,185) (OA at page 2, items 2 and 3).

As to claims 1, 4, 10, 11, 15, 16, 19 – 21, 24, and 25; the Freitas et al. surgical apparatus is used in laproscopic surgery. The Freitas et al. device comprises a probe having an instrument attached to one end, which is inserted into the patient. Slidably disposed over the probe is a sliding sleeve, which applies force to the instrument on the probe to affect the desired action. The claims as presently amended point out a substantial difference between the Freitas et al. device and the presently claimed surgical instrument. In contrast to the present inventions "...hollow manipulation shaft internally receiving a prime mover..." the Freitas et al. device utilizes a probe sleeve 28, which surrounds an immovable probe 52, which is attached to the instrument head 20. Operation of the Freitas et al. device is accomplished by moving the outer probe sleeve over probe 52 and against the instrument head 20 so that camming surfaces 40 and 42 are engaged by the inside of the probe sleeve 28 on the jaws 24 and 22.

In the Office Action mailed on August 4, 2003, the Examiner notes that "the claims as presently worded only require that the shaft receive a prime mover." (OA at page 4, item 12). Claims 1, 4, 10, 11, 15, 16, 19 – 21, 24, 25 and others, make clear, particularly after the instant

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amendments, that the present invention is directed to a surgical apparatus that incorporates, among other elements, a prime mover that is movably positioned internally within a hollow manipulation shaft. The prime mover, according to the present invention, is adapted to be activated by an actuator located at a proximal end of the shaft. In contrast, the Freitas et al. device utilizes the probe sleeve as the moving element to accomplish closure of the jaws 22 and 24.

It is well established that anticipation requires that each and every element of the applicant's claimed invention must be disclosed in a single prior-art reference. In re Paulson, 30 F.3d 1475, 31 U.S.P.Q.2d (BNA) 1671 (Fed. Cir. 1994); In re Spada, 911 F.2d 705, 15 U.S.P.Q.2d (BNA) 1655 (Fed. Cir. 1990). It follows that absence from the reference of any claimed element negates anticipation. Koster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 230 U.S.P.Q.2d (BNA) 81 (Fed. Cir. 1986). Anticipation will only arise where the description of the prior art invention is identically shown in as complete detail as is contained in the applicant's patent claim. Glaverbel S.A. v. Northlake Mkt'g & Supp., Inc., 45 F.3d 1550, 33 U.S.P.Q.2d (BNA) 1496 (Fed. Cir. 1995); Richardson v. Suzuki Motor Co., 868 F.2d 1226, 9 U.S.P.Q.2d (BNA) 1913 (Fed. Cir. 1989).

The utilization of a prime mover received internally within a hollow fixed manipulation shaft cannot be regarded as a simple design choice when contrasted with the fixed probe and moving sleeve of Freitas et al.

The design of a moving outer sheath violates basic medical principles of aseptic operation, in that, when the instrument has entered the body, the repetitive motion of the moving sleeve will tend to carry contamination from the skin or external environment into the body. In

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contrast, the moving parts of the instant invention are contained within the sterile interior of the apparatus, and do not carry contamination into the body.

From a strictly mechanical point of view, the moving external sleeve is inherently inferior in operation to that of the instant invention, and therefore again cannot be considered a design choice that does not affect functionality. In the Freitas et al. device, the exposed junction between the sleeve 28 over the probe 52 will repeatedly expose tissue near that junction to trauma. Soft tissues at the junction will be pinched and traumatized by the compression of the sleeve 28 against the instrument camming surfaces 40 and 42. Tissues may easily be caught in this exposed junction, and torn or otherwise further traumatized by rotation or other manipulation of the instrument.

The aforementioned camming action places the mechanism of Freitas et al. at severe disadvantage to that of the instant invention. As noted in Freitas et al. at Column 5, lines 2-5; "The angle of the offset [of the jaws] should not be so great as to impede probe sleeve 68 from slidingly engaging the camming surfaces and actuating the instrument." Examination of FIGS. 4 and 8 of Freitas et al. show immediately how this is so. If the angle at the camming surface is anything greater than a very slight acute angle, the sleeve and probe will meet at such an angle that high resistance, and impediment of operation, would be expected. If the angle of the tool jaws, relative to the axis of the probe, were to approach orthogonality, the device would not work at all. The instant invention contains no such disability. The internal moving shaft of the instant invention is not impeded in any fashion by any angle at which the instrument jaws may be placed. Instrument jaw angles of up to 180 degrees, relative to the axis of the prime mover, or even more, may be easily accommodated. This gives the tool a wide range opening widths. This

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is contrasted with the design of Freitas et al., which is clearly limited to tools, such as the vascular clip device envisioned, opening only a few degrees.

The substitution of an internal shaft for an external moving sheath simplifies and improves the functionality in another way. The use of a fixed probe 52 received within a moving sleeve 28 as disclosed by Freitas et al. in order to effect a camming action on the jaws 22 and 24, requires that the inside diameter of the sleeve 28 be considerably larger than the external diameter of the probe 52, as well seen in FIGS. 1, 3, 4, and 10. Additionally, the tools, disclosed in FIGS. 1, 2, 4, 8, and 9 are, due to the limitations of the camming mechanism, essentially flat in at least one dimension. This creates a substantial gap between the sides of the essentially flat tool and the rounded internal wall of the probe sleeve 28. As a result, there is considerable flow of gas and liquid retrograde alongside the probe 52 out of and away from the patient and towards the handle of the tool. This disadvantage is addressed at length from Col 3 line 67 to Col. 4 line 6 of the Freitas et al. patent. Such retrograde flow of gas, and also fluid in the case of joint arthroscopy which is traditionally performed under fluid seal, is such as to require the presence of a gasket 36.

In contrast, the instant invention is inherently much better sealed against retrograde fluid movement. As can be seen in FIGS 2, 4, 5, and 6, the prime mover 130 need only be very slightly smaller than the internal diameter of the hollow manipulation shaft 120. Accordingly, even a modestly close fit between these elements will substantially seal the passage. Since any tools appended to the instant invention do not depend on an external camming action, no large opening is required at the distal end of the prime mover 130. Should one skilled in the art find it desirable to add a gasket to increase the seal of the instant invention, such gasket would, as it needs to fill a much smaller space, have a greatly reduced gasket surface area exposed to blood

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and fluids compared to that of the Freitas et al. gasket 36, and would be more likely to present a positive and reliable seal.

The instant Office Action also misperceives an important difference between the instant invention and that of Freitas et al., in stating, "The mating portion of the tool [in Freitas et al.] may be described as having ...a lateral slot..." (OA at page 2 item 2). Freitas has no structure corresponding either physically or functionally to the lateral slot of the instant invention. As discussed at length below in section B.1, the device of Freitas et al. attaches to the shaft by means of a generally "T" shaped aperture that cooperates with a button shaped instrument flange 106. Such an arrangement allows the instrument head 20 to freely rotate about the button shaped instrument flange. As a result, the instrument head 20 on the Freitas et al. device is not only incapable of purposeful rotational movement, but it is likely to undesirably rotate during normal manipulation.

Accordingly, the rejection of claims 1, 4, 10, 11, 15, 16, 19 – 21, 24, 25, 29, 32, 36, and 37 under 35 U.S.C. §102(b) as being anticipated by Freitas et al. should be withdrawn.

B. Claim rejection under 35 U.S.C. §103

1. The instant invention provides a means of transmitting rotational force between the tool and the prime mover that is absent from the prior art, and that design imparts critical functional advantages that moves the related claims out of the area of an "unpatentable design choice...that would not change the functionality of the device."

The Examiner has rejected of claims 2, 3, 12, 13, 14, 17, 18, 26, 30, 31, 38 and 39 as being unpatentable over Freitas et al. (OA at page 3, items 5 and 6).

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The Examiner takes the position that, "it would have been obvious to one of ordinary skill in the art at the time of invention that the use of a coupler having a lateral slot or hook shaped tine as in the claims represents an unpatentable design choice over the coupler of Freitas et al. that would not change the functionality of the device." (OA at page 3, item 6, emphasis added) Applicant respectfully submits that the provision of a lateral slot engaged by a hook shaped tine considerably changes the functionality of the device envisioned by Freitas et al.

Claims 2, 3, 4, 8, 9, 10, 14, 15, 20, 21, 25, and 26 have been amended and these and other claims reflect that the invention, as disclosed, possesses a coupler and anchor that are capable of transferring rotational force. This claimed feature leads to both structural dissimilarity to, and numerous functional improvements over, the previously cited art of Freitas et al.

On a most basic level, the provision of an engagement portion that makes a mechanical connection at a substantially non-parallel angle to the axis of the prime mover, that is, the hook shaped tine engaged in the lateral slot, allows rotational force to be imparted and received by the tool. This functionality is completely absent from the Freitas et al. device. In Freitas et al., the tools, best exemplified by instrument head 114 seen in FIG. 8 or the scissor instrument body 240 illustrated in FIG. 9, attach to the distal end of the probe 104, seen best in FIG. 7. In all cases, the mechanism for attachment is a generally "T" shaped aperture that cooperates with a button shaped instrument flange 106. Contemplation of this mechanism will make it immediately apparent that such an attachment is incapable of transmitting any rotational force between the instrument flange 106 and the instrument head 114. As a result, an operator cannot, regardless of the type of instrument head employed, rotate the instrument head by turning the probe 104. Again, as discussed at length above in section A.1 the instrument head 114 of Freitas et al. may unpredictably and uncontrollably rotate about the button shaped instrument flange.

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In contrast, to the instant invention, the provision of a lateral slot 180 that is engaged by a generally hook shaped tine 190, allows rotation of the prime mover 130 to controllably rotate a tool at the distal end of the prime mover. One skilled in the art could envision a wide variety of tools whose operation would be substantially at right angles to the axis of the prime mover and how the operation of such tools would be facilitated by this feature.

Accordingly, the objection of the Examiner, that "...a lateral tine or hook...would in no way affect the functionality of the device and would be accurately described as design choices," (OA at age 4, item 13) is not correct in view of a lateral tine or hook interacting with a lateral slot. For these reasons, the Examiner's rejection of claims 2, 3, 12, 13, 14, 17, 18, 26, 30, 31, 38, and 39 should be withdrawn.

2. The frangible embodiments disclosed in the instant invention operate differently from those of the prior art, and possess considerable advantages that would not be obvious to one skilled in the art.

The Examiner has rejected claims 5, 6, 8, 9, 22, 23, 27, 28, 33, 34 and 40 – 42 under 35 U.S.C. §103(a) as being unpatentable over Freitas et al. in view of Chien (GB 227412A). Additionally, the Examiner has rejected claim 7 and 35 as being unpatentable over Freitas et al. as applied to claims 2 and 30. (OA at page 3, items 7-10).

The Chien reference is directed to a disposable dental explorer with a frangible handle. The disposable dental explorer has a plastic handle coupled to a stainless steel needle. The handle is provided with a neck portion having a reduced cross-sectional area.

Claims 4, 8, 9, 11, 12, 13, 15 have been amended and these and other claims reflect that the frangible portion of the instant invention has both structural and functional differences compared to the Freitas et al. and Chien devices.

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Structurally, the axis of fracture of the frangible portion of the instant invention runs orthogonal to the direction of translation of the coupler 140 and anchor 180. As a result, very little force is exerted across the axis of fracture during use, making the accidental rupture of the frangible portion highly unlikely. This is to be contrasted with the device of Chien, where force may easily be exerted across the axis of fracture of the frangible portion, that is, lateral force, thus making accidental rupture of the frangible portion much more likely during use.

Accidental rupture of the Chien frangible portion during use would instantly make the functional superiority of the design of the instant invention clear. In the Chien device, rupture of the frangible portion would lead to scattering of multiple small, sharp and dangerous fragments. These fragments could easily cause injury to the patient, the operator, or both. In the instant invention, the frangible portion is contained within the apparatus, and breakage fragments would be retained within the apparatus.

Secondly, in embodiments reflected in at least claims 4, 6, 8, 9, 11, and 12, the frangible portion 200 is non-releasably engaged to a part of the apparatus. In such embodiments, the tool may only be removed from the apparatus by breaking off the frangible portion from its attachment to the apparatus. It is only in such embodiments, as compared with the principle demonstrated by Chien that true one time use of an instrument can be guaranteed. Examination of the Chien device makes it clear that while the device can be broken in order to prevent cleaning, resterilization, and re-use; there is no particular need to do so. If the operator were to intentionally or carelessly subject the device to reuse, the frangibility of the device would have no more significance than that found in any disposable instrument that depends on the operator to, in fact, throw it away after use. In contrast, in those embodiments of the instant invention where the frangible portion non-releasably engages the apparatus, the apparatus cannot be

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effectively disassembled and cleaned, much less sterilized, without disassembly, and therefore breakage, of the frangible portion. Accordingly, there is a much greater likelihood that the frangible portion will have the desired effect of insuring one time use of the tool.

For these reasons, the Examiner's rejection of claims 5, 6, 7, 8, 9, 22, 23, 27, 28, 33, 34, 35, and 40 – 42 under 35 U.S.C. §103(a) as being unpatentable over Freitas et al. in view of Chien (GB 227412A) should be withdrawn.

Conclusion

In light of the amendment to the claims and these remarks, it is believed that each and every rejection raised by the Examiner has been overcome. It is the Applicant's position that the claims are in a condition for allowance. Allowance of the claims is respectfully solicited.

Should the Examiner have any questions or concerns prior to passing this case onto allowance, he is invited to contact the Applicants' undersigned representative.

Respectfully submitted,

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